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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,576	03/19/2004	Fred H. Miller	159.1001	7069

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
05/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/804,576	MILLER, FRED H.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2009 and 20 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,4,6,7,36-44,46,47,49-53,106-117,121,122,127,128,and 137-168* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/17/09 & 04/20/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 3,4,6,7,9,34-44,46,47,49-56,60-64,66,67,69-85,87,88,90,92,93,95-117,119,121,122 and 127-168.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 34,35,54-56,60-64,66,67,69-85,87,88,90,92,93,95-105,119, and 129-136.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 02/17/09 are acknowledged.

2. Claims 1-2, 5, 8, 10-33, 45, 48, 57-59, 65, 68, 86, 89, 91, 94, 118, 120, 123-126 were cancelled. Claims 6-7, 36-38, 46-47, 54-55, 60, 82-83, 87, 92-93, 108, 110, 112-116, 135, and 141-142 were amended. New claims 145-168 were added.

3. Claim 135 is dependent on claim 54, which is withdrawn. Therefore, claims 34-35, 54-56, 60-64, 66-67, 69-85, 87-88, 90, 92-93, 95-105, 119, 129-136 were withdrawn from consideration.

4. Claims 3-4, 6-7, 9, 36-44, 46-47, 49-53, 106-117, 121-122, 127-128, 135, and 137-168 are included in the prosecution.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on 02/17/09 and 04/20/09 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements.

See attached copy of PTO-1449.

Response to Arguments

Rejection of claims under 35 USC § 103(a)

6. Applicant's arguments, see Page 30, filed 02/17/09, with respect to the rejection of claims 1-2, 5-9, 36, 38, 41-53, 106-118, 121-122, 127-128 and 137-144 under 35 USC § 103(a) as being unpatentable over Nowak et al. (WO 01/03676) in view of

Zimmer (US 5,310,555) have been fully considered and are persuasive in light of the claim amendments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made over Bakhshaee et al. (WO 02/07710 A2.

7. Applicant's arguments, see Page 32, filed 02/17/09, with respect to the rejection of claims 3-4, 37 and 39 under 35 USC § 103(a) as being unpatentable over Nowak et al. (WO 01/03676) in view of Zimmer (US 5,310,555) and further in view of Rashid et al. (US 5,750,143) have been fully considered and are persuasive in light of the claim amendments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made over Bakhshaee et al. (WO 02/07710 A2.

8. Applicant's arguments, see Page 33, filed 02/17/09, with respect to the rejection of claim 40 under 35 USC § 103(a) as being unpatentable over Nowak et al. (WO 01/03676) in view of Zimmer (US 5,310,555) and further in view of Story (US 5,738,871) have been fully considered and are persuasive in light of the claim amendments. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made over Bakhshaee et al. (WO 02/07710 A2.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 3 recites the limitation "said cap" in line 2. Claim 3 is dependent on claim 141 and claim 141 does not mention a "cap". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

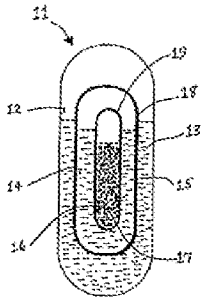
13. Claims 6-7, 9, 36, 41-44, 46-47, 49-53, 122, 127, 137-142, 145-156, 161-164, and 167-168 are rejected under 35 U.S.C. 102(e) as being anticipated by Bakhshaee et al. (WO 02/07710 A2).

The claimed invention is a multi-compartment capsule comprising a first receiving chamber comprising at least one ingredient in a liquid state in immediate release form, wherein the ingredient is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement; and a second receiving chamber comprising at least one ingredient in a solid state, formulated in a manner allowing for a time-delayed dissolution and release of the solid ingredient, wherein the ingredient is selected from

the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral. The ingredient of the first receiving chamber is different from the ingredient of the second receiving chamber. The multi-compartment capsule is a hard shell capsule.

Bakhshaee teaches an active principle delivery device comprising an inner capsule within an outer capsule, with at least the outer capsule is a hard capsule and the active ingredient in at least one of the capsules comprises a fluid (Abstract). Liquid forms of actives including an aqueous solution, suspension, micelle or emulsion are disclosed (Page 4, lines 26-32). The active principle is medicinal and/or nutritional (Page 7, lines 1-3). "At least a portion of the active principle may be a fluid either at or immediately prior to its time of use or during its manufacture" (Page 7, lines 23-25). The first "outer capsule is a hard capsule, the second, inner capsule may be a hard or soft capsule and each may be constructed from, for example, gelatin …" (Page 7, lines 27-30). In a preferred embodiment the second inner capsule is a hard capsule (Page 8, lines 1-2). "The delivery device may comprise more than one second, inner capsule within the first, outer capsule" (Page 8, lines 15-18). Active ingredients solids including powder, pellets or granules which may be coated or uncoated are disclosed (Page 8, lines 6-9).

FIGURE 2.



In Figure 2 Bakhshaee illustrates a triple capsule delivery device comprising a first, outer hard capsule 12 containing a liquid active principle 13, a second inner hard capsule 14 which also contains the same liquid active principle 15 as that contained in the outer hard capsule 12 and may be coated, as shown at 18. The second, inner hard capsule 14 also contains a third, inner hard capsule 16 which, in turn, contains the same active principle as that contained in the first and second, outer and inner hard capsule 12 and 14 but in solid particulate form. (Page 9, line 21 to Page 10, line 1). The outer hard capsule may be made from gelatin or hydroxy propyl methyl cellulose (HPMC) (Page 11, lines 5-9). Bakhshaee also teaches that it is “known to provide double, triple and, sometimes, quadruple therapies for the treatment of many conditions, wherein the inner and outer capsules can be provided in certain, but not all, combinations of solid and soft gel capsules containing the same or different active principles in solid or liquid form" (Page 4, lines 6-13). Bakhshaee teaches that “a further method of altering the release rate, and thus the absorbance profile, of an active principle, is to provide the same active principle in two or more different and distinct phases, for example solid and liquid within a single capsule” (Page 18, lines 16-20). Different active principles in the same delivery device are disclosed (Page 20, lines 8-17). The delivery device also allows for incompatible substances to be separated until such times as they are released or, to keep substances completely separated (Page 21, lines 23-27). Controlled release of the active principle is disclosed (Page 6, lines 10-31). Coating of the capsules in order to control delivery of the active is also disclosed (Page 19, lines 12-24).

Therefore, the limitations of claims 6-7, 9, 36, 41-44, 46-47, 49-53, 122, 127, 137-142, 145-156, 161-164, and 167-168 are anticipated by the teachings of Bakhshaee.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 3-4, 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakhshaee et al. (WO 02/07710 A2), in view of Rashid et al. (US 5,750,143).

The teaching of Bakhshaee is stated above.

Bakhshaee does not expressly teach a cap comprising a configuration to reduce dead volume space within the first receiving chamber.

Rashid teaches a controlled release capsule where “although conventionally shaped round caps may be used, the cap is preferably substantially flattened compared to conventional caps so as to accommodate a tablet whilst retaining the compact nature of the capsule by minimising dead space in the first volume” (Col. 2, lines 63-67).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an active principle delivery device comprising an inner capsule within an outer capsule and where at least one of the capsules comprises a fluid, as taught by Bakhshaee, reduce the dead volume space in the capsule by using a

cap with a different configuration, as suggested by Rashid, and produce the instant invention.

One of ordinary skill in the art would have been motivated to reduce the dead volume space in capsules in order to minimize oxidation and degradation of the active ingredients, improve shelf stability and maximize the dosing efficiency of each capsule. It would be obvious to one of ordinary skill in the art to try various configurations of the cap during the process of routine experimentation with a reasonable expectation of success in producing a functional and shelf-stable capsule-in-capsule dosage form.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 3-4, and 37-40, the limitation of the cap comprising a configuration adapted to reducing the dead volume space within the first receiving chamber would have been obvious over reducing the dead volume space by using a cap with a different configuration, as taught by Rashid (Col. 2, lines 63-67).

16. Claims 106-117, 121, 128, 143-144, 157-160, and 165-166 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakhshaee et al. (WO 02/07710 A2.

Bakhshaee teaches that the active principle is a medicinal and/or nutritional ingredient (Page 7, lines 1-3) and that different active principles in solid or liquid form

are known in the art to be incorporated into a single multi-compartment capsule (Page 4, lines 6-13).

Bakhshaee does not expressly teach the specific active ingredients.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an active principle delivery device comprising an inner capsule within an outer capsule and where at least one of the capsules comprises a fluid, as taught by Bakhshaee, use different medicinal and/or nutritional ingredients as the active ingredient in solid and liquid forms in different compartments of the capsule during the process of routine experimentation, and produce the instant invention.

One of ordinary skill in the art would find it obvious to try various combinations of active ingredients in different physical forms based on the desired therapeutic effect, for example, a combination of antioxidants such as the liquid vitamin E in one capsule and solid/powder vitamin C in another capsule, with a reasonable expectation of success in producing a functional multi-therapeutic product. Moreover, Bakhshaee teaches that it is known in the art to have double, triple and, sometimes, quadruple therapies for the treatment of many conditions, wherein the inner and outer capsules can be provided in certain, but not all, combinations of solid and soft gel capsules containing the same or different active principles in solid or liquid form" (Page 4, lines 6-13).

Regarding instant claims 106-117, 121, 128, 157-160 and 165-166, the recitations of the various active ingredient combinations would have been obvious over the double, triple and, sometimes, quadruple therapies for the treatment of many conditions, wherein the inner and outer capsules can be provided in certain, but not all,

combinations of solid and soft gel capsules containing the same or different active principles in solid or liquid form (Page 4, lines 6-13) and over the medicinal and/or nutritional ingredient (Page 7, lines 1-3), as taught by Bakhshaee. The recited active ingredients would have been obvious variants of combinations unless there is evidence of criticality or unexpected results.

Regarding instant claims 143-144, the limitation of the stability and sufficient shelf-life of the ingredients would have been obvious to one of ordinary skill in the art because during the process of routine experimentation, studies are routinely performed to determine the active ingredient stability, compatibility with other active ingredients and excipients, shelf life stability based on ICH guidelines, and organoleptic acceptance over time.

Conclusion

17. No claims are allowed.

18. Since the new rejections were necessitated by Applicant's amendment, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615